

REMARKS

Claims 1-25, 74 and 75 are pending in the application. An amendment to claim 1 is requested by this paper. Favorable reconsideration of the application is respectfully requested.

Claim Rejections under 35 U.S.C. §112

Claims 1-25, 74 and 75 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for the recitation “intermediate” in claim 1. The claim has been amended in an effort to further clarify that which is intended to be claimed. Further, in paragraph 7 of the Declaration Under 37 CFR 1.132 of co-inventor Ronald N. Zuckermann accompanying this response, Dr. Zuckermann addresses the issue of the clarity of this term in the context of the present application. Briefly, Dr. Zuckermann states, referring to the specification for example at page 1, line 15 to page 2, line 12 and at page 10, line 15 to page 11, line 12, that the ligands used in the supports of the present invention have binding characteristics that are intermediate in nature between those of the supports used in conventional separation techniques. The combination of multiple ligand constituents having different affinity characteristics allows for the tailoring of ligands that have greater specificity for a particular component or components of a biological sample than conventional general chromatography resin ligands (e.g., cations or anions (charge-based)), but less specificity than conventional affinity support ligands directed to a specific target or antigen (e.g., antibodies or antibody fragments (antibody-based)). This important feature of the ligands used in the supports of the present invention distinguishes them from those conventionally used on the basis that they have a binding affinity characterized by a specificity for a particular component(s) of a biological sample that is intermediate between the extremes characteristic of the ligands of the conventional very general or very specific supports previously available. Dr. Zuckermann concludes by stating that the recitation in amended claim 1 of “said ligand having a binding affinity characterized by a specificity for a component of a biological sample that is intermediate between charge based and antibody based ligands” refers to this important and distinguishing feature and would be clear and readily understood by those of skill in the art to which this invention pertains.

Accordingly, it is respectfully submitted that claim 1 and its dependents are clear and definite, and withdrawal of the rejections under 35 U.S.C. §112 is respectfully requested.

Claim Rejections under 35 U.S.C. §103

Claims 1-25 and 74-75 were rejected under 35 U.S.C. §103 as unpatentable over Zuckermann et al. (WO 98/42730).

The aspect of the invention presently claimed in the above-identified application is directed to a method for providing a biological sample component expression pattern for a biological sample. The method involves applying a biological sample to an affinity support composed of one or more ligands coupled to a biological sample-compatible matrix. As noted in the Summary section of the application at page 5, lines 1-19, in particular lines 1-4, and in the Detailed Description section of the application at page 10, line 15 to page 11, line 12, in particular page 10, line 16 to page 11, line 5, the affinity support materials of the invention have binding affinities characterized by intermediate specificities for biological sample components, as opposed to the very general or specific binding characteristics of conventional affinity support materials.

WO 98/42730 describes a substrate and technique for functionalizing that substrate to conduct screening of biological samples. It is focused on a substrate that can be used in either aqueous or organic media and a technique for functionalizing that substrate and does not provide any disclosure relating to the affinity/specificity characteristics of the binding between the ligands with which the substrate is functionalized and the samples run on that substrate that would teach or suggest the supports with ligands having binding affinity characterized by intermediate specificity of the invention described and claimed in the present application.

As noted above, the present invention is directed to a novel category of affinity support materials and, in the presently pending claims, techniques for their use in determining biological sample component expression patterns. Those of skill in the protein and nucleotide chemistry arts will appreciate that the support materials of the present invention differ significantly from the materials taught by the prior art for separating the components of biological samples, as the materials taught by the prior art use only very general and uncontrollable interactions with biological sample components (*e.g.*, charge-based) or very specific and controlled (*e.g.*, antibody-based) interactions, but nothing intermediate these extremes. The present invention provides this intermediate level of binding affinity. Claim 1 has been amended to further clarify this important feature of the present invention.

Thus, while WO 98/42730 identifies a variety of possible ligands for functionalization of the described substrates, there is no teaching that the ligands be selected and configured on the substrate to provide a binding affinity characterized by an intermediate level of specificity for components of a biological sample, as claimed. Such selection and configuration of ligands is detailed in the application and in recited in dependent claims 4-20. Without teaching to this effect, WO 98/42730 must be appropriately read to teach the use of ligands in a conventional manner on the inventive substrate. In paragraph 6 of the Declaration Under 37 CFR 1.132 of co-inventor Ronald N. Zuckermann accompanying this response, Dr. Zuckermann addresses this issue and states his belief that a person of skill in the art to which this invention pertains would

not consider the PCT application applicable to this important aspect of the present invention, and certainly not to render the invention of the present application obvious.

Accordingly, it is respectfully submitted that Zuckermann lacks any teaching or suggestion of this important feature of the claimed invention, it is respectfully submitted that claim 1, as amended, is patentable over the cited art. The remaining claims depend from claim 1 and are submitted to be patentable for at least the reasons noted for claim 1. Thus, withdrawal of the rejections under §103 is respectfully requested.

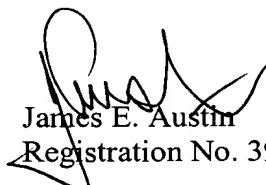
Dependent Claims

Claims 2-25, 74 and 75 depend from independent claim 1 and claim additional detail relating to certain aspects of the invention, namely, further characterization of the affinity support material ligands used and some specific ligands possessing binding affinity characterized by an intermediate level of specificity for components of a biological sample, in accordance with the present invention. It is respectfully submitted that the prior art provides no teaching or suggestion of ligands with the characteristics or constituents recited in these dependent claims, in particular claims 74-75 which were added in response to the prior office action, for use in connection with the claimed invention. Accordingly, it is respectfully submitted that the additional limitations recited in these claims provide an additional and independent basis for patentability of the claims, beyond that provided above with respect to claim 1.

Conclusion

Applicants believe that all pending claims are allowable and respectfully request a Notice of Allowance for this application from the Examiner. Should the Examiner believe that a telephone conference would expedite the prosecution of this application, the undersigned can be reached at the telephone number set out below. If any additional fees are due in connection with the filing of this amendment, the Commissioner is authorized to charge such fees to Deposit Account 500388 (Order No. CHIRP012).

Respectfully submitted,
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